

**REMARKS**

Claims 4, 6, 9-14, 44, and 45 were pending in this application before entry of the amendments made herein.

Claims 4, 9, and 10 has been amended for purposes of clarity. In particular, claims 4, 9, and 10 have been amended to delete all recitation of the term “functional fragment.”

Claim 4 also has been amended to add the proviso that the ErbB-3 protein is not the extracellular domain of ErbB-3. Written description support for this amendment is found in the specification as originally filed (for example, at paragraph spanning pages 12-13; and page 13, first full paragraph). Support for the proposition that claims can be properly amended to exclude one or more species of a genus when the specification provides a generic disclosure of the genus and numerous species within the genus, including the species being excluded from the scope of the claim, can be found in *In re Johnson*, 558 F.2d 1008, 1019, 194 U.S.P.Q. 187, 196 (C.C.P.A. 1977) (*see also* Section 2173.05(i) of the MPEP). Here, the specification provides a generic disclosure of the ErbB-3 proteins useful in the claimed method, and numerous species therein (see paragraph spanning pages 12-13; and page 13, first full paragraph). According to *Johnson*, the claims can be properly amended to exclude the use of an ErbB-3 protein that is the extracellular domain of ErbB-3.

No new matter has been added by these amendments. Upon entry of the present amendment, claims 4, 6, 9-14, 44 and 45 will be pending in the present application.

**I. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN**

Claims 6 and 6-14 remain rejected and claims 4, 44, and 45 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement (see Office Action, page 2, last paragraph). Specifically, the Examiner alleges that “the specification does not provide an adequate written description of ErbB-3 functional fragments that is required to practice the claimed invention” (see Office Action, page 7, third paragraph).

As a preliminary matter, Applicant wishes to state for the records that claims 7 and 8 were cancelled by means of the Amendment Under 37 C.F.R. § 1.111 filed March 2, 2009 (“March 2, 2009 Amendment”), and thus, were improperly rejected.

Applicant submits that the instant specification provides adequate written description of the genus “ErbB-3 functional fragments” by describing a representative number of ErbB-3

functional fragments (*e.g.*, SEQ ID NOS:3, 14 and 16) and their use in delaying or reducing tumor growth in inoculated mice compared to controls (see, *e.g.*, Tables 2-5). However, solely to expedite prosecution of this application, Applicant has amended the claims such that they recite specific ErbB-3 functional fragments. As amended, claim 4 recites an ErbB-3 protein that comprises (a) the amino acid sequence set forth in SEQ ID NO:3; or (b) amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14; or (c) amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16, wherein the ErbB-3 protein is not the extracellular domain of ErbB-3. The specification discloses these proteins and their use in preventing, treating or delaying neoplasm in a mammal (see page 12, second paragraph; and page 13, first full paragraph). Accordingly, Applicant submits that one skilled in the art would understand that the inventor, at the time the application was filed, had possession of the claimed invention. Withdrawal of the written description rejection is respectfully requested.

## **II. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b) SHOULD BE WITHDRAWN**

Claims 1, 4, 6, and 9-14 remain rejected and new claims 44 and 45 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 98/02540 to Fizpatrick *et al.* (“Fizpatrick *et al.*”). The Examiner contends that Applicant’s arguments in the March 2, 2009 Amendment are not persuasive, because Applicants argued limitations not recited in the claims (see Office Action, page 11, last paragraph). Specifically, the Examiner contends that while Applicants argued that Fizpatrick *et al.* does not teach a monomer of ErbB-3 protein, the claims are not limited to monomers of ErbB-3 proteins (see Office Action, page 11, last paragraph, lines 2-7). The Examiner also notes that “the ‘whereby’ clause of claim 4 does not require steps to be performed and does not limit the claim to a particular structure, therefore is not given weight” (see Office Action, page 12, first paragraph, last three lines). For the following reasons, Applicant submits that amended claim 4 and its dependent claims are not anticipated by Fizpatrick *et al.*

As a preliminary matter, Applicant wishes to state for the records that claim 1 was cancelled by means of the March 2, 2009 Amendment, and thus, was improperly rejected.

As amended, claim 4 recites a method for preventing, treating or delaying neoplasm in a mammal, which method comprises administering to a mammal an effective amount of an ErbB-3 protein that comprises (a) the amino acid sequence set forth in SEQ ID NO:3; or (b)

amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14; or (c) amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16, wherein the ErbB-3 protein is not the extracellular domain of ErbB-3. Fitzpatrick *et al.* does not teach or suggest any of the recited ErbB-3 proteins. At most, Fitzpatrick *et al.* discloses soluble chimeric heteromultimers containing the extracellular domain of ErbB-3 (see page 8, lines 25-27). However, claim 4 was amended to clarify that the ErbB-3 protein is not the extracellular domain of ErbB-3. Thus, Fitzpatrick *et al.* does not anticipate amended claim 4 and its dependent claims 6, 9-14, 44, and 45. Withdrawal of the rejections is respectfully requested.

### **CONCLUSION**

Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the present application. Withdrawal of the Examiner's rejections and an allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

If any additional fee is required for the submission of this response, please charge any such fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

REC. NO. 49,013

Date: September 11, 2009

Anthony C. Chen by [Signature] 38,673  
Anthony C. Chen (Reg. No.)  
**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, New York 10017  
(212) 326-3939